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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/634,399 08/09/00 PENA

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EXAMINER

WELLS, L

ART UNIT	PAPER NUMBER
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1619

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/634,399

Applicant(s)

PENA ET AL.

Examiner

Lauren Q Wells

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____ .
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-117 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-117 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
- 18) Interview Summary (PTO-413) Paper No(s) _____ .
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 111-117 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of hair loss, does not reasonably provide enablement for preventing of hair loss. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The disclosure of the present invention is directed to a method of treating or preventing hair loss as set forth in independent claims 111, 113, 115, and 117. A skilled practitioner in the art using the teachings of Samour (5,620,980), Pena (5,225,189), and Preuilh et al. (6,106,848) would be motivated to use Minoxidil to reduce or eliminate hair loss. However, preventing hair loss is inconsistent with what is known in the art since (1) reduction of hair loss indicates that

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hair loss is decreased, but not prevented; and (2) elimination of hair loss indicates that symptoms of hair loss may occur. Furthermore, prevention of hair loss indicates that the subject never experiences any characteristics associated with hair loss. Hence, the amount of guidance present in the specification, the absence of data indicating that the symptoms of hair loss do not occur when Minoxidil carried in composition is administered, and the state of the prior art indicating that the treatment using Minoxidil in composition is possible, all indicate that treatment, not prevention of hair loss is possible.

The amount of guidance necessary to perform Applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous conditions and amounts of Minoxidil in composition to determine what Minoxidil composition prevents hair loss. Hence, the amount of guidance present in the specification fails to present the necessary instruction such that one can readily determine the appropriate composition of claims 111, 113, 115, and 117.

Note: The Examiner reviewed Applicant's specification, but noted that the data does not indicate prevention of hair loss.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-24, 28, 61, 77-78, 84-85, and 104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(i) The phrases "derivative" and "derivatives thereof" in claims 23, 24, 28, 61, 77, 78, 84, 85, 104 are vague and indefinite, as it is not clear what other components the composition can comprise. The phrases are not described in the specification and one of ordinary skill in the art would not be appraised of them.

(ii) The phrase "preventing hair loss" in claims 111, 113, 115, and 117 is vague and indefinite, as it is not clear what this phrase is referring to. Does it mean reducing and/or eliminating, does it mean preventing, or does it mean something else?

(ii) The term "solvent tolerant" in claim 36 is a relative term which renders the claim indefinite. The term "solvent tolerant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-16, 21-27, 35-43, 46, 50, 57-61 rejected under 35 U.S.C. 102(b) as being anticipated by Samour (5,620,983).

Samour teaches a method for treating hair loss. Generally disclosed is a composition comprising 0.05-5% Minoxidil, 0-40% water, 0-90% lower alcohol, 0-98% lower glycol, and 0-

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5% thickening agent, which meets claims 1-8, 11-12, 36, 37, 38-41, 42-43, 46, 50, 57-61.

Specifically, a gel comprising 64.4% ethanol, 18.4% propylene glycol, water, 2%

hydroxypropylcellulose, and 1% minoxidil is disclosed, which meets claims 1-3, 7-16, 21-27, 35.

Specifically, a gel comprising 98% propylene glycol, 2.6% CARBOPOL 940, and 2% Minoxidil

is disclosed. A process of preparing the composition is disclosed, wherein the individual

ingredients are added together and mixed. See Col. 3, line 19-Col. 8, line 48;

Claims 36-38, 42-54, 56-57 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Pena (5,225, 189).

Pena teaches Minoxidil gels. Disclosed are gels comprising water, CARBOPOL 934P, 3% Minoxidil, 30% propylene glycol, 13% alcohol, and diisopropanolamine, which meets claims 36-38, 42-54, 56-57, 60. Disclosed is a process for preparing the composition comprising a) providing a solution comprising Minoxidil, a polyol, an alcohol, and neutralizing agent; b) providing a solution comprising carbomer and water; c) providing a composition comprising alcohol, neutralizer; d) combining part a) with part c); e) adding part b) to the combined solution and stirring. See Col. 1, line 35-Col. 6, line 63.

Claims 1, 3, 7-8, 11-14, 17-18, 21-30, 79-87, 90, 94-99, and 102-104 are rejected under 35 U.S.C. 102(e) as being anticipated by Preuilh et al. (6,106,848).

Preuilh et al. teach a composition comprising water, 0.1% hydroxypropylmethylcellulose, 47.5% propylene glycol, 0.5% active agent, 0.3% PREMULEN TR 2 (acrylate/C10-C30 alkyl acrylate), sodium hydroxide, and PEG-6 isostearate, wherein Minoxidil is disclosed as an active agent, which meets claims 1, 3, 7-8, 11-14, 17-18, 21-30, 79-87, 90, 94-99, 102-104.

CARBOPOL 1342 and 1382 (carbopol thickeners) and PEMULEN TR1 and TR2 (non-carbopol

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thickeners) are both disclosed as preferred crosslinked polymers. See Col. 1, line 64-Col. 3, line 60; Col. 5, line 3-Col. 8, line 44.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-19, 21-30, 33-54, 56-72, 74-87, 90-100 and 102-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samour in view of Preuilh et al. and Pena.

Samour fails to teach a neutralizing agent, a non-gel form, a non-carbopol acrylate/C10-C30 alkyl acrylate, and a stepwise process of preparing a composition (see above discussion).

Preuilh et al. is disclosed as discussed above.

Pena is disclosed as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Samour by substituting the PREMULEN TR 2 of Preuilh et al. for the CARBOPOL 940 because a) Samour and Preuilh et al. both teach compositions with Minoxidil as an active agent for the purpose of treating hair loss; b) PREMULEN and CARBOPOL are both acrylate/C10-C30 alkyl acrylate polymers; c) Preuilh et

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al. teach CARBOPOL and PREMULEN as interchangeable. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by substituting the diisopropanolamine of Pena for sodium hydroxide because a) Samour, Preuilh et al., and Pena all teach composition comprising Minoxidil as an active agent for the purpose of treating hair loss; b) Samour and Pena teach gel forms; c) sodium hydroxide and diisopropanolamine are both neutralizing agents that affect the pH of the composition.

Claims 1-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samour, Preuilh et al. and Pena in view of Grollier (5,059,606) and Mousa (6,171,604).

Samour, Preuilh et al., and Pena fail to teach 2-amino-2-methyl-1-propanol and inorganic thickeners (see above discussion).

Grollier et al. teach compositions that stimulate hair growth and reduce hair loss. Disclosed is a composition comprising 2% Minoxidil, 1% CARBOPOL 934, 4.5% propyleneglycol, 95% water, and 2-amino-2-methyl-1-propanol, which meets claims 36, 42-49. Also disclosed is a composition comprising 2g Minoxidil, 95g ethanol, and 3 g propyleneglycol. Minoxidil is disclosed as comprising between 0.05 and 10% of the composition. See Col. 3, line 58-Col. 7, line 22.

Mousa teaches honey preparations that are effective in promoting hair growth, preventing/minimizing hair loss, and treating alopecia. Cellulose derivatives, synthetic macromolecules such as vinyl or acrylic groups, bentonites, and colloidal silicas are disclosed as thickeners. See abstract; Col. 2, line 14-line 50; Col. 3, line 40-Col. 8, line 46; Col. 10, line 40-Col. 12, line 13.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of the combined references by substituting the 2-amino-2-methyl-1-propanol of Grollier et al. for diisopropanolamine because a) the combined references and Grollier et al. both teach compositions with Minoxidil as an active agent for the purpose of treating hair loss; b) 2-amino-2-methyl-1-propanol and diisopropanolamine are disclosed as neutralizing agents that affect the pH of compositions. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by substituting the inorganic thickeners of Mousa for the thickeners of the combined references because a) the combined references and Mousa both teach compositions for the treatment of hair loss; b) Mousa teaches cellulose derivatives, vinyl and acrylate polymers, and inorganic thickeners as interchangeable; c) the combined references teach hydroxypropylcellulose (a cellulose derivative) as a thickener, and CARBOPOL and PERMULEN (acrylic group polymers) as thickeners; d) Mousa teaches that where the presence of the oil phase is less important, the thickener can be inorganic.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Prior Art

The prior art made of record and not specifically relied upon in any rejections cited above is either 1) considered cumulative to the prior art that was cited in a rejection or is 2) considered pertinent to the applicant's disclosure and shows the state of the art in its field but is not

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determined by the Examiner to read upon the invention currently being prosecuted in this application.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
June 7, 2001



DAMERON L. JONES
PRIMARY EXAMINER